REMARKS/ARGUMENTS

The Office Action mailed February 7, 2007, has been received and reviewed. Claims 1 through 35 are currently pending in the application. Claims 1 through 35 stand rejected. Applicants have amended claims 1, 15-17, and 30, have cancelled claims 13 and 18, and respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 4,806,343 to Carpenter et al.

Claims 1 through 4, 8 through 12, 17, and 30 through 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Carpenter et al. (U.S. Patent No. 4,806,343). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-4, 8-12, 17, and 30-32, either directly or via dependency, recite the limitation of claim 13, which was acknowledged to be nonanticipated by Carpenter in the Office Action. As such, Applicants respectfully request withdrawal of the present rejection.

Anticipation Rejection Based on U.S. Patent No. 6,267,958 to Andya et al.

Claims 1 through 4, 17, 20, 22, 24, 26, and 30 through 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Andya et al. (U.S. Patent No. 6,267,958). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 1-4, 17, and 30-32, either directly or via dependency, recite the limitation of claim 13, which was acknowledged to be nonanticipated by Carpenter in the Office Action. As such, Applicants respectfully request withdrawal of the present rejection.

Anticipation Rejection Based on U.S. Patent No. 4,816,440 to Thomson

Claims 30 through 32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Thomson (U.S. Patent No. 4,816,440). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 30-32, either directly or via dependency, recite the limitation of claim 13, which was acknowledged to be nonanticipated by Carpenter in the Office Action. As such, Applicants respectfully request withdrawal of the present rejection.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 4,806,343 to Carpenter et al. Taken in View of U.S. Patent No. 6,267,958 to Andya et al.

Claims 1 through 12, 17, 20 through 26, and 30 through 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpenter et al. (U.S. Patent No. 4,806,343) taken in view of Andya et al. (U.S. Patent No. 6,267,958). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Claims 1-4, 8-12, 17, and 30-32, either directly or via dependency, recite the limitation of claim 13, which was acknowledged to be nonobvious by the combination of Carpenter and Andya in the Office Action. Specifically, the claims recite a polypeptide is selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily that is stable in near neutral pH environments at temperatures up to and exceeding physiological conditions. In view of the foregoing, Applicants respectfully request withdrawal of the present rejection.

Obviousness Rejection Based on U.S. Patent No. 4,806,343 to Carpenter et al. and U.S. Patent No. 6,267,958 to Andya et al. and Further in View of U.S. Patent No. 4,816,440 to Thomson

Claims 1 through 12, 17, 20 through 28, and 30 through 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpenter et al. (U.S. Patent No. 4,806,343) and Andya et al. (U.S. Patent No. 6,267,958), as applied to claims 1 through 12, 17, 20 through 26, and 30 through 32 above, and further in view of Thomson (U.S. Patent No. 4,816,440). Applicants respectfully traverse this rejection, as hereinafter set forth.

Claims 1-12, 17, 20-28, and 30-32, either directly or via dependency, recite the limitation of claim 13, which was acknowledged to be nonobvious by the combination of Carpenter, Andya, and Thomson in the Office Action. Specifically, the claims recite a polypeptide is selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily that is stable in near neutral pH environments at temperatures up to and exceeding physiological conditions. In view of the foregoing, Applicants respectfully request withdrawal of the present rejection.

Obviousness Rejection Based on U.S. Patent No. 4,806,343 to Carpenter et al., U.S. Patent No. 6,267,958 to Andya et al. and U.S. Patent No. 4,816,440 to Thomson, and Further in View of U.S. Patent No. 5,861,284 to Nishimura et al. and U.S. Patent No. 5,128,242 to Arimura et al.

Claims 1 through 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpenter et al. (U.S. Patent No. 4,806,343), Andya et al. (U.S. Patent No. 6,267,958), and Thomson (U.S. Patent No. 4,816,440), as applied to claims 1 through 12, 17, 20 through 28, and 30 through 32 above, and further in view of Nishimura et al. (U.S. Patent No. 5,861,284) and Arimura et al. (U.S. Patent No. 5,128,242). Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claims 1, 15-17, and 30 have been amended to recite a polypeptide selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily (or, in the case of claim 16, a pituitary adenylate cyclase polypeptide) that is stable in near neutral pH environments at temperatures up to and exceeding physiological conditions. The relied upon references are all drawn to preserving biological activity of particular proteins during and after a freze-drying (or lyophilization) process, particularly during the thawing, freezing and rehydration process. None

of the references teaches or suggests preparing the particular stabilized polypeptide particles that are stable in near neutral pH environments at temperatures up to and exceeding physiological conditions. As outlined in the Background section of Carpenter, freeze-drying creates very particular instability problems in proteins that lead to loss of activity. None of the cited references teaches or suggests overcoming problems with protein degradation at neutral pH environments and at temperatures up to and exceeding physiologic conditions, such as those encountered by implantable polypeptides.

As acknowledged in the Office Action, the combination of Carpenter, Andya, and Thomson do not teach or suggest polypeptides selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily that are stable in near neutral pH environments at temperatures up to and exceeding physiological conditions. To overcome this deficiency, the Examiner relies on Nishimura as disclosing a composition for stabilizing polypeptides with an amide at their C-terminal or a disulfide linkage in the molecule. (Office Action at pg. 11). However, Nishimura is limited to a disclosure of a method of producing a fused parathyroid hormone having cysteine at its N-terminal and a cysteine-free peptide ligated to the N-terminal. Applicants respectfully submit that Nishimura does not overcome the deficiencies of the claims (as amended). In view of the foregoing, Applicants respectfully request withdrawal of the present rejection.

ENTRY OF AMENDMENTS

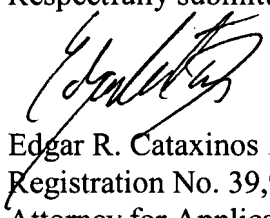
The amendments to claims 1, 15-17, and 30 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application.

CONCLUSION

Claims 1-12, 14-17, and 19-35 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues

remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



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